UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE RELAFEN ANTITRUST LITIGATION) Master File No. 01-CV-12239-WGY)
STATE OF MARYLAND, et al.,) 04 11726 WGY
Plaintiffs)
v.)
SMITHKLINE BEECHAM CORPORATION)
and)
SMITHKLINE BEECHAM PLC,)
Defendants.)

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered by and between the following Parties as defined below: (i) Participating States and (ii) Defendants;

WHEREAS, in August 2004, Plaintiff States filed suit against defendants SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK") and SmithKline Beecham, plc (hereafter collectively "Defendants") in the United States District Court for the District of Massachusetts and intend to file an Amended Complaint, a true and correct copy of which is attached as Exhibit A;

WHEREAS, Participating States have alleged that Defendants unlawfully obtained their patent protection for Relafen through fraud on the United States Patent and Trademark Office and unlawfully excluded generic competition through sham patent litigation against generic manufacturers, all in violation of section 2 of the Sherman Act and state antitrust and/or unfair

competition laws and Participating States have conducted an investigation relating to the claims and underlying events alleged in Participating States' initial and Amended Complaints and as a result, are familiar with the liability and damages aspects of the claims asserted therein:

WHEREAS, the Defendants contest the Participating States' initial and Amended Complaint and allegations therein and contend instead that the '639 patent was properly and lawfully obtained from the U.S. Patent and Trademark Office and properly asserted against generic nabumetone producers:

WHEREAS, as a result of arms-length negotiations, the Parties have determined that it is in their mutual best interests to resolve the dispute to avoid the expense, delay, and uncertainty of protracted and complex antitrust litigation;

NOW, THEREFORE, WITNESSETH, this Agreement is intended by the Parties to fully, finally, and forever resolve, discharge, and settle the Released Claims, as defined herein upon and subject to the terms and conditions set forth below. This Agreement is without admission or concession by any Party as to the merit of the Parties' respective positions or as to any alleged violation of law.

I. **DEFINITIONS**

As used in this Agreement, the following shall have the meanings specified below:

- (a) "Court" means the Honorable William G. Young, or if he is unavailable, another judge of the United States District Court for the District of Massachusetts.
- (b) "Defendants" means SmithKline Beecham Corporation, d/b/a GlaxoSmithKline and SmithKline Beecham plc.

- (c) "Effective Date" means 45 days after the date this Agreement is signed by authorized representatives for Defendants and State Liaison Counsel.
- (d) "Final Order" means the Stipulated Order of Dismissal attached as Exhibit B to this Agreement.
- "Nabumetone Products" means Relafen and/or its AB-rated generic (e) bioequivalent.
- (f) "Non-participating State" means each state, commonwealth or territory of the United States that declines to become a signatory to this Agreement on or before the Effective Date.
- "Participating States" means each undersigned state, commonwealth or (g) territory of the United States of America that joins in and executes this Settlement Agreement on or before the Effective Date in its sovereign capacity and on behalf of its respective state agencies.
 - "Parties" means Participating States and the Defendants; (h)
- "Plaintiff States" means the States of Maryland, Arkansas, Oregon, Idaho, (i) Washington and Illinois.
- (j) "Relafen" means the prescription drug nabumetone sold under the trademark Relafen®.
- (k) "Relafen End Payor Settlement" means the Fourth Amended Stipulation and Agreement of Settlement by and between the End Payor Plaintiffs and GSK in In re Relafen Antitrust Litigation, No. 01-CV-12239 WGY (D. Mass).

- (l) "Released Claims" means all manner of claims, demands, actions, suits, causes of action, damages whenever incurred, liabilities of any nature whatsoever, including costs, expenses, penalties and attorneys' fees, known or unknown, suspected or unsuspected, in law or equity, that the Participating States, or any of them, ever had, now have, or hereafter can, shall or may have, directly, representatively, derivatively or in any other capacity and which are either asserted in the States' Complaint or which arise out of the conduct, events or transactions, prior to the date hereof, asserted in the States' Complaint involving the pricing or purchase of, or the enforcement of intellectual property related to, the drug Relafen or its generic form, nabumetone.
- (m) "Released Parties" means Defendants and their present and former direct and indirect parents, subsidiaries, divisions, partners and affiliates, and their respective present and former stockholders, officers, directors, employees, managers, agents, attorneys and any of their legal representatives (and the predecessors, heirs, executors, administrators, trustees, successors and assigns of each of the foregoing).
- (n) "Relevant Period" means the period from September 1, 1998 through June 30, 2003.
- (o) "Settlement Administrator" means the person at the State of New York

 Office of the Attorney General chosen by Participating States.
- (p) "Settlement Fund" or "Settlement Amount" means the sum of ten million dollars (\$10,000,000), or such lesser amount as may be determined in accordance with the provisions of Paragraph IV below, plus all interest or other income that accrues thereon.

 GSK shall pay interest at the rate of 1.5% per annum on the Settlement Amount from

January 1, 2005 - February 8, 2005, for a total of \$16,027.39. The Settlement Amount shall be paid as provided in Paragraph III.

- "State Agencies" means the current and former state departments, state (q) bureaus, state agencies, and other state governmental entities that the undersigned State Attorneys General represent in this Settlement Agreement. All employee benefit plans, self insured or otherwise, and all Medicaid Health Maintenance Organization claims, to the extent they are included within the Relafen End Payor settlement, are excluded.
- "State Liaison Counsel" means the Attorneys General of the States of New (r) York and Maryland.
- "States' Complaint" means the complaint filed by the Plaintiff States on (s) August 3, 2004, amended as reflected in Exhibit A, the allegations of which may be further amended only as necessary to add additional Participating States to the action.

II. **AGREEMENT**

The Parties agree to compromise, settle and resolve fully and finally on the terms set forth herein, all Released Claims.

SETTLEMENT PAYMENT III.

- Defendants shall pay the Settlement Amount to the Participating States in (a) full and final satisfaction of all Released Claims.
- Unless this Agreement is terminated, as provided in Paragraph IV, the (b) Settlement Amount shall be paid by certified check or by wire transfer to the Settlement Administrator in full, complete and final settlement of the Released Claims as provided herein, within seven (7) business days of the Effective Date of this Agreement.

Defendants' transfer of the Settlement Amount to the Settlement Administrator shall satisfy Defendants' obligation to make payments under this Agreement. Defendants shall not have any liabilities, obligations or responsibilities with respect to the investment, payment, disposition or distribution of the Settlement Fund after such transfer.

- (c) Within three days of the transfer of the Settlement Amount to the Settlement Administrator, State Liaison Counsel shall file with the Court the Final Order a copy of which is attached as Exhibit B.
- (d) The Settlement Administrator shall not distribute, remove, loan or dissipate in any form the Settlement Funds until entry of the Final Order by the Court. The Settlement Administrator shall have the authority to invest the monies in the Settlement Fund in short term federally insured investments. Under no circumstances shall the Defendants or Settlement Administrator be held liable for any increases or decreases of the Settlement Fund.
- (e) The apportionment and distribution of the funds shall be determined exclusively by the Attorneys General of the Participating States.

IV. SETTLEMENT PAYMENT OR TERMINATION

- (a) If, by the Effective Date, Participating States representing 80% of the total sales of Relafen by GSK to the fifty states (less West Virginia) during the Relevant Period have not become signatories to this Agreement, Defendants shall have the option, in their unfettered discretion, to
 - (1) terminate this Agreement; or

(2) proceed with this Agreement but reduce the Settlement Amount by a percentage equal to GSK's sales of nabumetone to Non-participating States as a percentage of GSK sales of nabumetone to all states (e.g., if sales to Nonparticipating States represent 30% of GSK's sales to all states, the Settlement Amount would likewise be reduced by 30%, or to \$7,000,000).

Filed 04/13/2005

- If, by the Effective Date, Participating States representing more than 80%, (b) but less than 100%, of the total sales of Relafen by GSK to the fifty states (less West Virginia) during the Relevant Period, have become signatories to this Agreement, the Settlement Amount shall be reduced by the percentage of GSK sales of nabumetone to all states accounted for by GSK sales of nabumetone to the Non-participating States.
- For purposes of this Paragraph, GSK's sales to states shall be determined (c) from Medicaid expenditure data found at http://www.cms.hhs.gov/medicaid/drugs/ drug5.asp.

V. RELEASE

Upon transfer of the Settlement Amount to the Settlement Administrator, (a) the Participating States shall release and forever discharge the Released Parties from the Released Claims. Each Participating State hereby covenants and agrees that it shall not, hereafter, seek to establish liability against any Released Party based, in whole or in part, on any of the Released Claims. The Parties do not intend to release or otherwise affect in any way any rights a Participating State has or may have against any other party or entity whatsoever other than the Released Parties with respect to the Released Claims. In addition, the Released Claims shall not include any claims arising in the ordinary course of business between the Participating States and the Released Parties concerning product liability, breach of contract, breach of warranty, or personal injury. Furthermore, the Released Claims shall not include any claim Participating States may have that does not arise from the facts, matters, transactions, events, occurrences, acts, disclosures, statements, omissions or failures to act set forth in the States' Complaint, such as claims involving "best price," "average wholesale price," "wholesale acquisition cost," reporting practices or Medicaid fraud or abuse; provided, however, that in such litigation GSK preserves its right to assert that any recovery by the Participating States in such litigation involving the drug Relafen should be set off by the pro rata share received from the Settlement Fund and the Participating States reserve the right to assert that there should be no set-off.

(b) In addition, each Participating State hereby expressly waives and releases, upon transfer of the Settlement Amount, any and all provisions, rights and benefits conferred by § 1542 of the California Civil Code, which reads:

Section 1542. General Release; extent. A general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor;

or by any law or any state or territory of the United States, or principle of common law, which is similar, comparable or equivalent to § 1542 of the California Civil Code. Each Participating State may hereafter discover facts other than or different from those which it knows or believes to be true with respect to the Released Claims but each Participating State hereby expressly waives and fully, finally and forever settles and releases, upon transfer of the Settlement Amount, any known or unknown, suspected or unsuspected, contingent or non-contingent Released Claims with respect to the subject matter of this Paragraph V unless intentionally concealed or hidden, without regard to the subsequent discovery or existence of such different or additional facts.

QUALIFIED SETTLEMENT FUND VI.

The Settlement Fund maintained by the Settlement Administrator is intended by the parties hereto to be treated as a single "qualified settlement fund" for federal income tax purposes pursuant to Treas. Reg. § 1.468B-1, and to that end, the parties hereto shall cooperate with each other and shall not take a position in any filing or before any tax authority that is inconsistent with such treatment. Whether or not the Effective Date has occurred, and whether or not the Settlement Fund qualifies as a qualified settlement fund within the meaning of Treas. Reg. § 1.468B-1, the Settlement Administrator shall cause to be paid from the Settlement Fund any taxes or estimated taxes due on any income earned on the funds in the Settlement Fund and all related costs and expenses. The parties elect that the Settlement Fund should be treated as a "qualified settlement fund" from the earliest possible date and agree to make any "relation back" election that may be available. If amounts received by a Participating State or by Defendants upon any Settlement Payment or Termination, are construed to be income, it is the recipient's sole responsibility to pay taxes on the amount construed to be income, plus any penalties or interest.

VII. MISCELLANEOUS

- (a) This Agreement and attached Exhibits contain the entire agreement and understanding of the Parties. There are no additional promises or terms of the Agreement other than those contained herein. This Agreement shall not be modified except in writing signed by all of the Participating States and Defendants or by their authorized representatives.
- (b) The Parties: (1) acknowledge that it is their intent to consummate this Agreement; and (2) agree to cooperate and exercise their best efforts to the extent reasonably necessary to effectuate and implement all terms and conditions of the Agreement.
- (c) The Parties agree that the Settlement Amount, and the other terms set forth in this Agreement were negotiated in good faith by the Parties, and reflect a settlement that was reached voluntarily after investigation, consultation with experienced legal counsel and arms-length negotiations.
- (d) Neither this Agreement nor any act performed or document executed pursuant to or in furtherance of the Agreement is or may be used as an admission of, or evidence of: (1) the validity of any Released Claim, or of any wrongdoing or liability of the Defendants, or (2) any fault or omission of the Defendants in any civil, criminal or administrative proceeding in any court, administrative agency or other tribunal.
- (e) This Agreement shall be binding on, and shall inure to the benefit of, the Parties hereto and their successors and assigns. The Parties expressly disclaim any

intention to create rights which may be enforced by any other person under any circumstances.

- All signatories to this Agreement, by their signature, expressly represent (f) that they are fully authorized to execute this Agreement for the Party they represent, including without limitation, all who are encompassed within the definitions of the Participating States or Defendants, on whose behalf the signatory is executing this Agreement. This Agreement may be executed on separate signature pages or in counterparts with the same effect as if all Parties had signed the same instrument.
- (g) Except as otherwise provided in this Agreement, neither the Participating States nor Defendants shall have the right to withdraw from this Agreement once the Settlement Agreement has been executed by the Parties.
- (h) Any failure by any Party to insist upon the strict performance by any other Party of any of the provisions of this Agreement shall not be deemed a waiver of any of the provisions hereof, and that Party, notwithstanding that failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Agreement to be performed by the other Party.
- (i) This Agreement, including, but not limited to, the Released Claims contained herein, shall be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts without regard to its conflict of laws principles. The Parties to this Agreement agree that the Final Order shall provide that the Court shall retain jurisdiction to enforce all provisions and terms of this Agreement. This Agreement shall be enforced in the United States District Court for the District of Massachusetts. The

Parties waive any objection that each of them may now or hereafter have to the venue of any such suit, action or proceeding and irrevocably consent to the jurisdiction of the Court and agree to accept and acknowledge service in any such suit, action or proceeding.

- (j) The Parties agree and acknowledge that the monies paid as part of this Agreement do not constitute, nor shall they in any way be deemed a payment of a penalty or a fine of any kind. The Parties further acknowledge and agree that Defendants' payment of the Settlement Amount described in this Agreement is strictly for compensatory damages and/or equitable relief. Participating States have not included the imposition of criminal or civil fines or penalties (or payments in lieu thereof) as part of this Settlement Agreement.
- (k) The headings used in this Agreement are intended for the convenience of the reader only and shall not affect the meaning or interpretation of this Agreement in any manner.

IN WITNESS WHEREOF, the Parties have entered into this Agreement by affixing the signatures of their authorized representatives below.

J. JOSEPH CURRAN, JR. Attorney General Ellen S. Cooper Chief, Antitrust Division

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Dated:

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Counsel for Defendants

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Counsel for Defendants

IN WITNESS WHEREOF, the Parties have entered into this Agreement by affixing the signatures of their authorized representatives below.

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Dated: 2/15/05

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Counsel for Defendants

Signature block for Plaintiff State of Alabama of Settlement between and among Plaintiff States and GlaxoSmithKline, plc in In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

Dated: February 1,2005 Montgomery, Alabama

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Dated: January 11, 2005 Anchorage, Alaska

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Signature block for Plaintiff State of Arizona of Settlement between and among Plaintiff States and GlaxoSmithKline, plc in In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

Dated: February 18, 2005 Phoenix, Arizona

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Signature block for Plaintiff State of Colorado Complaint and settlement between Plaintiff States and Defendants in State of Maryland, et al. v. SmithKline Beecham Corp., et al., (D.Mass.) 01-CV-12239-WGY

Dated: February 14, 2005

JOHN W. SUTHERS Attorney General

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Dated: February 11, 2005 Wilmington, Delaware

> M. Jane Brady Attorney General

By: Michael A. Undorf

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Signature block for Plaintiff District of Columbia of Settlement between and among Plaintiff States and GlaxoSmithKline, plc in In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

Dated: February 5, 2005 Washington, DC

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Signature block for Plaintiff State of Florida of Settlement between and among Plaintiff States and GlaxoSmithKline, plc in In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

Dated: February 14, 2005 Tallahassee, Florida

Charles J. Crist, Jr. Attorney General of Florida

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Dated: March/5, 2005 Atlanta, Georgia

THURBERT E. BAKER

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Signature block for Plaintiff State of Hawaii of Settlement between and among Plaintiff States and GlaxoSmithKline, plc in *In re Relafen Antitrust Litigation*, Master File No. 01-12239-WGY

Dated February 17, 2005 Honolulu, Hawaii

> Mark J. Bennett Attorney General

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Signature block for Plaintiff State of Idaho of Settlement between and among Plaintiff States and GlaxoSmithKline, plc in *In re Relafen Antitrust Litigation*, Master File No. 01-12239-WGY

Dated: January 12, 2005

Boise, Idaho

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Document 5

Dated: March 18, 2005 Chicago, Illinois

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Dated: February 17, 2005

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Dated:

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Signature block for Plaintiff State of Maine of Settlement between and among Plaintiff States and GlaxoSmithKline, plc in In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

Dated: February 3, 2005

Augusta, Maine

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Dated: February 16, 2005 Boston, Massachusetts

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Dated: February 11, 2005 St. Paul, Minnesota

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Dated: February 11, 2005 Jackson, Mississippi

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Dated: February 10, 2005 Jefferson City, Missouri

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Dated: January 11, 2005 Helena, Montana

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Date: February 14, 2005

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Dated: February 23, 2005

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Dated: March 4, 2005

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Dated: January 31, 2005

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In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

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Dated: February 18, 2005

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RELAFEN ANTITRUST LITIGATION

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Dated: February 8, 2005

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Dated: February 11, 2005

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Settlement Agreement Between Plaintiff States and GlaxoSmithKline: Relafen

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By and Among Plaintiff States and GlaxoSmithKline, plc,
In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

Dated: February 17, 2005 Harrisburg, PA

Respectfully submitted,

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for settlement between and among Plaintiff States and GlaxoSmithKline, plc in In re Relafen Antitrust Litigation, Master File No. 01-12239-WGY

Dated: March _____, 2005 San Juan, Puerto Rico

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Dated: January 19, 2005 Pierre, South Dakota

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Dated: January 25, 2005

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Dated: January 12, 2005 Austin, Texas

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Dated: February 23, 2005 Salt Lake City, Utah

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Dated: February 16, 2005 Montpelier, VT

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Signature block for Plaintiff Territory of the United States Virgin Islands for Settlement between and among Plaintiff States and Territories and GlaxoSmithKline, plc in *In re Relafen Antitrust Litigation*, Master File No. 01-12239-WGY. Authority for this action is found in Title 3, Chapter 8, Section 114 of the Virgin Islands Code.

Dated: March 21, 2005 St. Thomas, VI

Respectfully submitted,

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Dated: March 3, 2005 Richmond, Virginia

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Dated: February 14, 2005 Seattle, Washington

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Dated: March __ , 2005 Plaintiff, State of Wyoming,

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UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE RELAFEN ANTITRUST LITIGATION	
STATE OF MARYLAND by Attorney General J. Joseph Curran, Jr. Office of the Attorney General Antitrust Division 200 St. Paul Street Baltimore, MD 21202) Master File) No. 01-CV-12239 WGY) 04 11726 WGY)
STATE OF ARKANSAS by Attorney General Mike Beebe Antitrust Division 323 Center St. Ste. 200 Little Rock, AR 72201))))
STATE OF IDAHO)
by Attorney General Lawrence Wasden Office of the Attorney General Len B. Jordan Building 650 W. State St., Lower Level Boise, ID 83720-0010))))
STATE OF ILLINOIS By Attorney General Lisa Madigan 100 West Randolph Street, 13th Floor Chicago, Illinois 60601))))
) STATE OF OREGON)

STATE'S AMENDED COMPLAINT

PAGE

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)
STATE OF WASHINGTON)
by Attorney General Christine O. Gregoire)
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Seattle, Washington 98164,)
Seattle, washington 98104,)
(O.I. DI : (100 C) ())
(Other Plaintiff States))
71.1.100)
Plaintiffs)
)
v.)
)
SmithKline Beecham Corporation)
One Franklin Plaza)
16th and Race Streets)
Philadelphia, PA 19102,)
)
And)
)
SmithKline Beecham plc,	,
One Franklin Plaza	,
16 th and Race Streets	,)
Philadelphia, PA 19102,))))))
)
Defendants.))
To ATAITMMIND!	,

STATES FIRST AMENDED COMPLAINT

Plaintiffs, the States, Commonwealths, and Territories, (specification of Plaintiff States)

STATE'S AMENDED COMPLAINT

PAGE

Case 1:04-cv-11726-WGY

I. <u>INTRODUCTION</u>

- 1. Relafen® is a brand-name prescription drug containing nabumetone as its active pharmaceutical ingredient. Relafen® is a non-steroidal anti-inflammatory drug ("NSAID"), used to treat diseases characterized by inflammation, and a chemical compound disclosed by U.S. Patent No. 4,420,639 (the "'639 Patent"). Prior to August 2001, no other brand-name or generic nabumetone-based drug was marketed in the United States, due to the Defendants' anticompetitive conduct including unlawfully obtaining and enforcing a monopoly for Relafen® and nabumetone-based drugs through intentional misrepresentation to the U.S. Patent and Trademark Office ("PTO"). In 2002, GSK's sales of Relafen® in the United States were over \$200 million.
- 2. Defendants obtained a patent for nabumetone and had it listed in the Food and Drug Administration's (FDA) Orange Book, defined below, which enabled Defendants to falsely create and extend their monopoly for Relafen® and nabumetone. Defendants further engaged in sham litigation to unlawfully enforce their patent, even though they knew that the patent was invalid. As a result, consumers were forced to pay more for nabumetone.
- 3. Plaintiff States seek the following: a) a finding that Defendants' actions violated federal and state antitrust laws, consumer protection laws, unfair competition laws and other related state laws; b) a permanent injunction preventing Defendants from submitting the '639 Patent for listing in the *Orange Book* and from taking other actions similar to those which

resulted in the improper delay in generic competition for nabumetone; and c) relief for injuries sustained as a result of Defendants' violations of law.

Document 5

II. PARTIES

- 4. Defendant SmithKline Beecham Corporation is a corporation organized and existing under the laws of the commonwealth of Pennsylvania, doing business as GlaxoSmithKline ("SmithKline"). Its principal place of business is at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania 19102. SmithKline develops, manufactures, markets, sells, and distributes pharmaceutical products, including Relafen®.
- 5. Defendant SmithKline Beecham plc is a corporation organized and existing under the laws of the United Kingdom, and is a corporate affiliate of SmithKline Beecham Corporation ("Beecham"). Its principal place of business within the United States is at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania 19102. Both SmithKline Beecham Corporation and SmithKline Beecham plc are hereinafter referred to as "GSK" or "Defendants." Defendants manufacture and market Relafen® throughout the United States.
- 6. The States bring this action by and through their Attorneys General (a) in their proprietary capacities on behalf of represented entities which may include state departments, bureaus, agencies, political subdivisions, and other government entities as direct or indirect purchasers, and/or as assignees of the antitrust causes of action of intermediate purchasers through which they procured or reimbursed for such drugs, or as purchasers under medical or pharmaceutical reimbursement programs, of Relafen® or any other nabumetone based drug during the relevant period (hereinafter "State Governmental Entities"), (b) in their capacities as enforcers of state law to enjoin violations, to disgorge unjust profits, and to provide relief for injuries incurred in their states by securing damages and/or restitution, injunctions and other equitable remedies. Plaintiff State of Illinois also brings this action, by and through its Attorney General, under federal and state law, in its sovereign capacity, as parens patriae on behalf of

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natural persons who paid for Relafen® or any other nabumetone product during the relevant time period.

III. JURISDICTION AND VENUE

- 7. Subject matter jurisdiction is proper pursuant to Section 2 of the Sherman Act, 15 U.S.C. § 2, and sections 4, 4C, 12 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 15c, 22 and 26, and under 28 U.S.C. §§ 1331, 1337.
- 8. In addition to pleading violations of federal antitrust law, the States also allege violations of state antitrust, consumer protection and/or unfair competition statutes and related state laws, as set forth below, and seek damages, civil penalties and/or equitable relief under those state laws. All claims under federal and state law are based upon a common nucleus of operative facts, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction of the non-federal claims under 28 U.S.C. § 1367(a), and under the principles of supplemental jurisdiction. Supplemental jurisdiction will avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness.
- 9. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). Defendants transact business in this district. Further, the claims alleged arose, in whole or in part, in this judicial district, and a substantial portion of the affected trade and commerce described below has been carried out in this judicial district.

IV. STATEMENT OF FACTS

A. Pioneer Drugs

10. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., a drug

STATE'S AMENDED COMPLAINT

PAGE

Case 1:04-cv-11726-WGY

355(j).

- 11. The NDA must contain, among other things, data on the composition of the drug product including its active ingredient, the means for its manufacture, and a statement of its proposed uses. An NDA must list all patents that claim the approved drug where a claim of patent infringement could reasonably be asserted against an unauthorized manufacturer or seller of the drug. 21 U.S.C. § 355(b) and (c)).
- 12. A pioneer drug is typically covered by one or more patents, which grant the owner the right to exclude others from manufacturing for sale the new drug for the duration of the patent(s) including any extensions of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman" or "Hatch-Waxman Act").
- Once the NDA is approved, and upon certification by the brand-name 13. manufacturer that the newly-issued patent meets the listing criteria, the FDA publishes the patent information submitted by the manufacturer in a publication commonly referred to as the Orange Book. See 21 U.S.C. § 355(j)(7)(a)(iii) (formally titled, "Approved Drug Products with Therapeutic Equivalent Evaluations"). The FDA has a long-standing, publicly announced policy of accepting at face value the accuracy of patent information it receives from a patent holder, and its eligibility for Orange Book filing.
- Once approved, a new drug may be labeled, marketed and advertised only for 14. FDA-approved uses. A pharmacist filling a prescription must fill the prescription with the drug brand specified by the physician, unless an FDA-approved generic version is available and

applicable state law provides for generic substitution.

B. Generic Drugs

- 15. A generic drug is one that has been approved by the FDA as bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.
- 16. Generic drugs are usually priced substantially below the brand-name drug.

 Typically, the first generic drug to be sold is priced at a percentage discount off the brand-name drug price, and even steeper price reductions occur as additional generic versions become available.
- 17. A brand-name drug generally loses substantial market share to generic competition within a relatively short time after a generic is introduced to the market. Consumers covered by some form of insurance or benefit plan often switch to a generic bioequivalent and may be encouraged to do so by virtue of a lower co-payment for generics. Consumers who pay cash for prescriptions also switch from brand-name to generic drugs to obtain the lower price.
- 18. A principal goal of the Hatch –Waxman Act is to facilitate generic competition by streamlining the process by which manufacturers of generic drugs receive regulatory approval to bring their products to market. *See Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998). Under Hatch-Waxman, a company may seek expedited FDA approval to market a generic version of a brand-name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. § 355(j). An ANDA filer relies on the safety and efficacy data already filed with the FDA by the brand-name manufacturer. 21 U.S.C. § 355(j)(2)(A)(I).
- 19. In its ANDA, a generic manufacturer generally must certify to the FDA that one of the following conditions is satisfied: (i) no patent covering the drug has been filed with the

FDA ("Paragraph I Certification"); (ii) the patent for the brand-name drug has expired ("Paragraph II Certification"); (iii) the patent for the brand-name drug will expire on a particular date, and the generic company does not seek to market its generic product before that date ("Paragraph III Certification"); or (iv) the patent for the brand-name drug is invalid or will not be infringed by the generic company's proposed product ("Paragraph IV Certification"). 21 U.S.C. § 355(i)(2)(A)(vii).

- Pursuant to a Paragraph III or Paragraph IV Certification, the Hatch-Waxman Act 20. allows ANDA applicants to perform all necessary testing, to submit an application for approval. and to receive tentative approval before the relevant patents covering the brand-name pioneer drug expire. Upon the patents' expiration and receipt of FDA final approval, the generic drug companies may market their generic versions of the brand-name drug.
- 21. If the generic manufacturer submits a Paragraph IV certification, it must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If the patent holder fails to initiate an infringement suit within forty-five days of receipt of the notice, FDA approval of the ANDA proceeds without regard to patent issues. However, if a patent infringement suit is brought within the forty-five day window, the FDA is automatically barred from approving the ANDA until the earliest of thirty months after the patent holder's receipt of the Paragraph IV certification, the patent expires, or a final judicial determination of non-infringement. 21 U.S.C. § 355(j)(5)(B)(iii).

C. <u>Defendants' Anticompetitive Conduct</u>

Defendants Made Intentional Misrepresentations to the PTO and Engaged in Sham Litigation to Obtain and Maintain an Improper Monopoly for Relafen® and Nabumetone

22. Defendants own the '639 Patent which purported to cover the chemical compound nabumetone. Pursuant to NDA No. 19-583, Defendants marketed Relafen®, whose active ingredient is nabumetone, in the United States and elsewhere since February 1992. The '639 8

Patent resulted from filing of six U.S. patent applications, and ultimately expired on December 13, 2002.

- 23. Copley Pharmaceutical, Inc. ("Copley"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Eon Labs Manufacturing, Inc. ("Eon") (collectively the "Generic Manufacturers") each manufacture generic pharmaceutical products. Each filed an ANDA with the FDA to market generic versions of Relafen®.
- 24. On August 4, 1997, Copley filed ANDA No. 75-179, the first ANDA for a generic version of the Relafen® 750 mg tablet with a Paragraph IV Certification that the '639 Patent was either invalid or not infringed.
- 25. On August 18, 1997, Teva filed ANDA No. 75-189, the first ANDA for a generic version of the Relafen® 500 mg tablet with a Paragraph IV Certification that the '639 Patent was either invalid or not infringed. Teva acquired Copley on August 10, 1999, consolidating the ANDAs for both the 500 mg and 750 mg strengths of generic Relafen®.
- 26. On December 18, 1997, Eon filed ANDA 75-280 for a generic version of the Relafen® 500 mg and 750 mg tablets with a Paragraph IV Certification that the '639 Patent was either invalid or not infringed.
- 27. The Generic Manufacturers each gave written notice ("notice of certification") to Beecham, pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii), that their ANDAs and the accompanying certification had been filed with the FDA.
- 28. Defendants sued for infringement of the '639 Patent within forty-five days of the notices of certification (hereinafter referred to collectively as the "Infringement Actions"). Upon filing of the first suit, a 30-month stay of the FDA's authority to grant final marketing approval to the Generic Manufacturers was granted. Final approval could not be given to Teva's and Copley's ANDAs until either they prevailed in the Infringement Actions, or the 30-month stay

expired.

- 29. The Infringement Actions were consolidated for all purposes and captioned as In re '639 Patent Litigation, Civil Action No.97-12416-RCL (D. Mass.) and were assigned to the Honorable Reginald C. Lindsay.
- 30. The Generic Manufacturers claimed that the '639 Patent was invalid because nabumetone was anticipated by prior art, namely a 1973 article by scientists J.N. Chatterjea and R. Prasad entitled "Condensation of Mannich Base Salts with Phenols: Orientation of Adducts," published in the Indian Journal of Chemistry, Volume 11 at 214-18 (March 1973) (the "Chatterjea & Prasad publication"). The Generic Manufacturers argued that the Chatterjea & Prasad publication identified and enabled nabumetone and therefore anticipated all claims set forth in the '639 Patent, either explicitly or inherently. They also claimed that the '639 Patent was unenforceable because Beecham breached its duty of candor to, and engaged in inequitable conduct before, the PTO. In re '639 Patent Litigation, 154 F.Supp. 2d 157, 160 (D.Mass. 2001).
- 31. At all relevant times, Defendants knew that the '639 Patent was not their intellectual development, was anticipated by prior art, and that the '639 Patent was not enforceable because Defendants and their representatives had knowingly made material misrepresentations to the PTO in connection with the prosecution of that patent.
- 32. Nonetheless, Defendants commenced, prosecuted, and maintained the sham Infringement Actions against the Generic Manufacturers and defended against their counterclaim suits for the improper purpose of maintaining a monopoly in the sale of nabumetone-based prescription drugs in the United States ("Relevant Market"), and to conceal that unlawful interference and monopoly maintenance.
- 33. Defendants continued to maintain the sham *Orange Book* listing, the Infringement Actions, and their sham defenses of the counterclaim suits knowingly, intentionally,

affirmatively, with the purpose of unlawfully maintaining their monopoly in the Relevant Market, and with the effect of affirmatively and continuously foreclosing the Generic Manufacturers and any other competitors from the Relevant Market.

- 34. The FDA granted tentative approval to Eon's ANDA No. 75-280 on August 8, 1998, for nabumetone 500 mg and 750 mg tablets, and to Teva's ANDA No. 75-189 for nabumetone 500 mg and 750 mg tablets on December 24, 1998. This tentative approval reflected the FDA's determination that all the criteria for ANDA "Final" approval had been satisfied, except for the resolution of issues relating to patents or the 180-day exclusivity period. Final approval could not be granted until either the resolution of pending patent infringement litigation or the expiration of the 30-month stay.
- 35. Final approval was granted on May 26, 2000 to Teva's ANDA No. 75-189 for nabumetone 500 mg tablets, and on June 6, 2000 to Copley's ANDA No. 75-179 for nabumetone 750 mg tablets.

The Court's Ruling Invalidating The '639 Patent

- On August 14, 2001, Judge Lindsay invalidated the '639 Patent due to prior art 36. and anticipation. The Court also held that the '639 Patent was unenforceable because the Defendants made material misrepresentations to the PTO.
- 37. The Court then found that the material misrepresentations made by Defendants were made with the intent of deceiving the PTO and entered judgment in favor of the Generic Manufacturers and against SmithKline and Beecham for patent invalidity and unenforceability.
- 38. Defendants appealed that decision, which was affirmed on August 15, 2002, on the grounds that the patent was invalid because it had been anticipated by prior art. SmithKline Beecham Corp. v. Copley Pharmaceutical, Inc., No. 01-1611, 2002 WL 1890708 (Fed. Cir. Aug. 15, 2002). The Court of Appeals did not reach the issue of inequitable conduct. *Id.* Defendants'

post-appeal petitions were denied.

- 39. Teva began selling a 500 mg generic version of Relafen® on or about August 20, 2001. Teva began selling its 750 mg generic version on or about September 26, 2001.
- 40. Throughout the course of the proceedings before the PTO and for much of the litigation of the Infringement Actions, Defendants knowingly, willfully and fraudulently concealed the true facts about the Chatterjea & Prasad publication, their knowledge of the existence of prior art, and their misrepresentations to the PTO in order to wrongfully obtain the '639 Patent and to prevent and discourage lawful competition. Thus, Plaintiff States were prevented from discovering the Defendants' illegal conduct.

V. <u>RELEVANT MARKET</u>

- 41. The relevant product market is the manufacture and sale of nabumetone-based prescription drugs. The relevant geographic market is the United States, including its commonwealths, territories, and protectorates as a whole.
- 42. The only seller of prescription drugs containing nabumetone in the United States could impose a significant, non-transitory price increase without losing sales sufficient to render the price increase unprofitable, as demonstrated by the Defendants' ability to charge supracompetitive prices for nabumetone during the period in which Relafen® lacked generic competition.
- 43. A material change in the price of nabumetone relative to that of other NSAIDs would not induce patients to switch. Other NSAIDs are not reasonably considered viable substitutes for Relafen® and generic nabumetone. Each NSAID may cause a variety of side effects, the most common of which are gastrointestinal side effects. Relafen® and generic nabumetone may produce gastrointestinal and other side effects, but in a manner and extent

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44. Until approximately August 20, 2001, Defendants were the manufacturers and sellers of prescription drugs containing nabumetone in the United States. Their share of the Relevant Market was 100%.

VI. TRADE AND COMMERCE

- 45. Throughout the relevant period, Relafen® was sold throughout the United States. Relafen® and nabumetone were transported across state lines and sold in each of the Plaintiff States.
- 46. Defendants' activities, including manufacturing, marketing, distributing and selling Relafen® and nabumetone were in the regular, continuous, and substantial flow of interstate commerce, and have had, and continue to have, a substantial effect upon interstate commerce.

VII. MARKET EFFECTS

- 47. Defendants' illegal conduct had the purpose or effect of, or the tendency or capacity to, unreasonably restrain and injure competition by preventing the entry of generic nabumetone.
- 48. Absent Defendants' anticompetitive conduct, at least one generic competitor would have begun marketing a generic version of nabumetone well before August 2001.
- 49. If a generic competitor had been able to enter the Relevant Market and compete with Defendants, the State Governmental Entities (as payors, purchasers, and reimbursers) would have been free to substitute -- and would have substituted -- a lower-priced generic for the higher-priced brand-name drug.
- 50. By preventing generic competitors from entering the market, Defendants deprived Plaintiff States of the competition that the federal and state antitrust laws, consumer protection laws and/or unfair competition statutes and related state laws are designed to promote, preserve, and protect.

VIII. <u>INJURY</u>

- 51. But for Defendants' anticompetitive acts, the State Governmental Entities and Illinois consumers would have been able to purchase a generic nabumetone product at a far lower price than the monopoly prices maintained by Defendants, and beginning at an earlier time.
- 52. As a direct and proximate result of the unlawful conduct alleged above, Plaintiff States, including their State Governmental Entities and Illinois consumers, were not able to purchase, or pay reimbursements for purchases of, nabumetone products at prices determined by free and open competition, and consequently have been injured in their business and property in that, *inter alia*, they have paid more and continue to pay more for nabumetone products than they

would have paid in a free and open competitive market.

53. As a direct and proximate result of the unlawful conduct alleged above,
Defendants have unjustly profited through inflated profit margins and have thus far retained the illegally obtained profits.

X. <u>ALLEGATIONS UNDER FEDERAL LAW</u>

COUNT I

(Violations of Section 2 of the Sherman Act)

- 54. Plaintiff States repeat each and every preceding allegation as if fully set forth herein.
- 55. At all relevant times, Defendants maintained monopoly power in the Relevant Market.
- 56. As described above, Defendants knowingly and willfully engaged in conduct designed to unlawfully obtain and extend their monopoly power in the Relevant Market. These actions included, among others, (i) intentionally submitting false patent information to the FDA; (ii) intentionally submitting fraudulent statements to, and omitting material facts from, the PTO; (iii) prosecuting baseless, sham patent litigation against the Generic Manufacturers; and (iv) maintaining sham defenses to the counterclaims by the Generic Manufacturers.
- 57. Defendants' Infringement Actions were objectively baseless due to, *inter alia*, the presence of the Chatterjea & Prasad publication, and therefore constituted sham litigation.

 Further, the purpose of Defendants' notification in bringing the actions was to directly interfere with the ability of the Generic Manufacturers to market less expensive generic versions of Relafen® to compete with the brand-name product.
 - 58. Defendants' illegally created and maintained monopoly power in the Relevant

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Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

- 59. Defendants' conduct in unlawfully obtaining and maintaining a monopoly in the market for Relafen® and nabumetone injured the Plaintiff States in their business or property. Plaintiff States, including State Governmental Entities, were deprived of the ability to purchase less expensive, generic versions of Relafen® and paid higher prices for nabumetone-based products than they would have paid, absent Defendants' unlawful conduct.
- Defendants' anticompetitive and unlawful conduct alleged herein has injured 60. competition in the Relevant Market by obtaining and maintaining their power to exclude competitors, reduce output, charge monopoly prices, reap monopoly profits and otherwise thwart competition in the Relevant Market.

COUNT II

(Unjust Enrichment)

- Plaintiff States repeat each and every preceding allegation as if fully set forth 61. herein.
- 62. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Defendants' unlawful acts include improperly listing their patent in the Orange Book; submitting fraudulent misrepresentations to, and concealing material facts from the PTO; filing and pursuing baseless patent infringement actions; and maintaining baseless defenses to counterclaims at the expense of the Plaintiff States and Illinois consumers.
- The overcharges and unlawful monopoly profits derived by Defendants through 63. charging supracompetitive and artificially inflated prices for Relafen® are the direct and proximate result of Defendants' unlawful practices.
- The financial benefits derived by Defendants rightfully belong in substantial part 64. to the Plaintiff States and Illinois consumers.

- 65. It would be inequitable and unjust for Defendants to be permitted to retain any of the unlawful proceeds resulting from their fraudulent, illegal, and inequitable conduct.
- 66. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff States and Illinois consumers.

SUPPLEMENTAL STATE LAW CLAIMS

- 67. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Plaintiff States, as set forth below.
- damages as permitted by state law, for their injuries caused by these violations pursuant to federal and state law as set forth below. Plaintiff States also seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through the use of the invalid '639 Patent is unlawful. Plaintiff States further seek equitable and injunctive relief to correct for the anti-competitive market effects and other harms to purchasers caused by the unlawful conduct of Defendants, and other relief so as to assure that similar conduct does not occur in the future.

 69. Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 70. Defendants' acts violate, and Plaintiff State of Arkansas is entitled to relief under, the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 et seq. and the Arkansas Unfair Practices Act, Ark. Code Ann. §§ 4-75-201, et. seq. 4-75-301, et. seq.
- 71. Plaintiff State of Delaware repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 72. Defendants' acts violate, and/or Plaintiff State of Delaware is entitled to relief under, the Delaware Antitrust Act, 6 *Del.C.* § 2101 *et seq.*, the Delaware Consumer Fraud Act, 6 *Del.C.* § 2511 *et seq.*, and the Uniform Deceptive Trade Practices Act, 6 *Del.C.* § 2511 *et seq.*
- 73. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 68.

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- 74. Defendants' acts violate, and Plaintiff State of Idaho is entitled to relief under the Idaho Competition Act, *Idaho Code §§ 48-101 et seq*.
- 75. Plaintiff State of Illinois repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 76. Defendants' acts violate, and Plaintiff State of Illinois is entitled to relief under the Illinois Antitrust Act, 740 ILCS 10/1 et seq., including without limitation 740 ILCS 10/3(3). The Illinois Attorney General possesses authority to settle and release consumer claims in a parens patriae or other representative capacity. This authority to represent consumers has been judicially recognized, and the functional equivalent of parens patriae authority has been expressly conferred by the state legislature.
- 75. Plaintiff State of Louisiana repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 76. Defendants' acts violate, and Plaintiff State of Louisiana is entitled to relief under the LSA R.S. 51:122 et seq.; 51:1401 et seq.
- 77. Plaintiff State of Maryland repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 78. Defendants' acts violate, and Plaintiff State of Maryland is entitled to relief under the Maryland Antitrust Act, Md. Com. Law Code Ann. § 11-201, et seq. (2000).
- 79. Plaintiff State of Oregon repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 80. Defendants' acts violate, and Plaintiff State of Oregon is entitled to relief under the Oregon Antitrust Act, ORS 646.705, et seq.
- 81. Plaintiff State of South Dakota repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 82. Defendants' acts violate, and Plaintiff State of South Dakota is entitled to relief under, S.D. Codified Laws ch. 37-1.
- 83. Plaintiff State of Texas repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 84. Defendants' acts violate, and Plaintiff State of Texas is entitled to relief under the Texas Free Enterprise and Antitrust Act, Texas Business and Commerce Code § 15.01, et seq."
- 85. Plaintiff State of Washington repeats and realleges each and every allegation contained in paragraphs 1 through 68.
- 86. Defendants' acts violate, and Plaintiff State of Washington is entitled to relief under, Wash. Rev. Code 19.86 RCW.
- 87. Plaintiff State of Wisconsin repeats and realleges each and every allegation contained in paragraph 1 through 68.
- 88. Defendants' acts violate, and Plaintiff State of Wisconsin is entitled to relief under, Wis. Stat. § 133.03 and Wis. Stat. § 133.16-18

(Additional supplemental State law claims and statutory authority to be added) RELIEF REQUESTED

Accordingly, the Plaintiff States pray that this Court:

- 89. Adjudge and decree that Defendants engaged in conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.
- 90. Adjudge and decree that Defendants engaged in conduct in violation of the state statutes and state laws set forth in this Complaint;
- 91. Enjoin and restrain, pursuant to federal and state law, Defendants, their affiliates, assignees, subsidiaries, successors and transferees, and the officers, directors, partners, agents and employees, and all other persons acting or claiming to act on their behalf or in concert with them, from engaging in any conduct and from adopting any practice, plan, program or device having a similar purpose or effect to the anticompetitive actions set forth above;
- 92. Award the Plaintiff States all damages sustained by and permitted to be recovered by the States (as direct purchasers, assignees of direct purchasers or as indirect purchasers) and for all additional damages, penalties and other monetary relief provided by applicable law, including treble damages;
- 93. Award Plaintiff States such other equitable relief, including, but not limited to, restitution and disgorgement, as the Court finds necessary to redress Defendants' violations of federal and state law;
- 94. Award Plaintiff State of Illinois all damages sustained by its consumers, and all additional damages, penalties and other monetary relief provided by applicable law, including treble damages.
 - 95. Award to each Plaintiff State the maximum civil penalties allowed by law;
 - 96. Directing such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff States demand a trial by jury.

DATED: February _____, 2005

Respectfully submitted, PLAINTIFF STATES

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UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE RELAFEN ANTITRUST LITIGATION)) Master File) No. 01-CV-12239-WGY)
STATE OF MARYLAND, et al.,) 04 11726 WGY
Plaintiffs)
v.)
SMITHKLINE BEECHAM CORPORATION)
and)
SMITHKLINE BEECHAM PLC,)
Defendants.	,)

ORDER OF DISMISSAL

AND NOW, this ____ day of February, 2005, upon review of the Settlement Agreement by and among the Parties, it is hereby ORDERED as follows:

- 1. The Court finds that the Settlement Fund is a "qualified settlement fund" as defined in section 1.468B-1(c) of the Treasury Regulations in that it satisfies each of the following requirements:
- (a) The Settlement Fund is established pursuant to an order of this Court and is subject to the continuing jurisdiction of this Court;
- (b) The Settlement Fund is established to resolve or satisfy one or more claims that have resulted or may result from an event that has occurred and that has given rise to at least one claim asserting liabilities, and

- (c) The assets of the Settlement Fund are segregated from other assets of GSK, the transferor of payments to the Settlement Fund, and the Settlement Administrator.
- 2. Under the "relation-back" rule provided under section 1.468B-1(j)(2)(i) of the Treasury Regulations, the Court finds that:
- (a) The Settlement Fund met the requirements of paragraphs 1(b) and 1(c) of this Order prior to the date of this Order approving the establishment of the Settlement Fund subject to the continued jurisdiction of this Court; and
- (b) GSK and the Settlement Administrator may jointly elect to treat the Settlement Fund as coming into existence as a "qualified settlement fund" on the later of the date the Settlement Fund met the requirements of paragraphs 1(b) and 1(c) of this order or January 1 of the calendar year in which all of the requirements of paragraph 1 of this Order are met. If such relation-back election is made, the assets held by the Settlement Fund on such date shall be treated as having been transferred to the Settlement Fund on that date.
- 3. All claims in Civil Action No. 04-11726 WGY are DISMISSED WITH PREJUDICE. Each party is to bear its own costs.

SO ORDERED:

William G. Young Chief Judge